The Reuse of Single-Use Devices

FDA Proposed Strategy: Concept in Development

Beginning of Practice

- Reuse of Reusable Devices Started in 1960s
- Advent of Single Use Only Devices in Early 1980s
- Economics is Driving Force for Reprocessing
- Hospital v. Third-Party Reprocessing
- Most Frequently Reprocessed Single-Use Devices

FDA's Position Historically

- Reprocessing in Hospitals/Clinics (Compliance Policy Guide 300.500)
- Any Person Engaged in Single Use Device Reprocessing is a "Manufacturer"
- Premarket Submissions Have Not Been Requested

FDA's Position Historically
(continued)

- Requirements of 3rd Party Reprocessing Firms:
  - Device Registration and Listing, 21 CFR, Part 807
  - Good Manufacturing Practice (GMP) Inspection, 21 CFR, Part 820
  - Medical Device Reporting, 21 CFR, Part 803
  - General Labeling Requirements, 21 CFR, Part 801
- Reuse Policy Documents & Correspondence on FDA Web Page (www.fda.gov.reuse)

Simple Solutions?

- One voice in the debate suggests calling for identical regulatory controls for reprocessing as for OEMs - call for 510(k)s and PMAs
- An opposing voice suggests we leave General Controls in place as sufficient: Registration and Listing, GMP (Quality System Requirements), Labeling, and Medical Device Reporting
- Neither approach is satisfactory

Problems to Solve

- Lack of evidence of public health problems does not mean that the current practice is safe and effective
- This system inside hospitals and in third parties has grown over time with FDA tacit acceptance
- Reuse is basically a problem of economics and ethics: both are outside of FDA mandate!

Some Guiding Principles

- Capitalize on what we do best: understanding of regulatory control and devices
- Our constraints suggest the importance of partnering/outside leveraging: show leadership but do not solve all by ourselves
- Do not let the perfect serve as the enemy of the good

Regulatory Strategy by Risk

Product Risk Category	Regulatory Requirements	Enforcement Date
"High-Risk" Products	**R & L; Premarket submissions or Cease reprocessing**	**Immediate enforcement action within 6 months**
"Moderate-Risk" Products	**R & L; Collect postmarket data on S & E; Declare conformance or file 510 (k)**	**R & L – 6 mos Submissions to FDA within 2 years**
"Low-Risk" Products	**R & L**	**Within 1 year**

How do we get there?

- Four committees working rapidly:
  - **Steering (Kessler)**
  - **Policy (Ng)**
  - **Categorization (Zimmerman)**
  - **Research (Merritt)**
- Milestones
  - **Strategy paper: October**
  - **Teleconference: Nov. 10**
  - **Public Meeting: Dec 14**
  - **Product specific Guidance : February, 2000**
  - **Enforcement: Spring, 2000**

Possible Roles for Standards

- Standardized methods for cleaning, disinfection, sterilization
- Verification of sterility
- Measurement of endotoxins
- Verification of device performance after reprocessing

Critical Premarket Issues

- How to establish device specifications to ensure device is (as) safe and effective
- How to detect changes to devices by OEM and the need for revalidation
- Ability to perform thorough process definition and validation studies given facility and sterilizer limitations

Vision for the Future

Current Reality

- Widespread practice with little data on safety or effectiveness
- Single use labels not clearly meaningful
- Single use labels don't identify vulnerabilities
- Patients are not informed - experimentation?

Future Vision

- FDA regulatory approach will be RISK and SCIENCE based
- Single use labels will have clinical relevance
- Single use labels will identify vulnerabilities
- Horizontal and vertical standards critical
- Leverage outside parties